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Dated: May 31, 2011
Electronic Signature for Kari Lynn Barnes: /Kari Lynn Barnes/

Docket No.: 101672.0019P
(PATENT)
EFS-WEB

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:
Guy Rome

Application No.: 10/803,512 | Confirmation No.: 5437

Filed: March 18, 2004 | Art Unit: 3763

For: MULTIFUNCTION ADAPTOR FOR AN OPEN-ENDED CATHETER | Examiner: Q. H. Vu

APPEAL BRIEF

MS Appeal Brief - Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

This is an appeal of the Final Office Action, mailed September 28, 2010, filed under 37 C.F.R. § 1.191. This brief follows the Notice of Appeal, filed December 21, 2010, and the subsequent Notice of Panel Decision from Pre-Appeal Brief Review, mailed March 1, 2011, which set a deadline of April 1, 2011 for the filing of an Appeal Brief. This brief is filed with a two-month extension of time to extend the deadline for response to June 1, 2011. Accordingly, this brief is timely filed.

This brief contains items under the following headings as required by 37 C.F.R. § 41.37 and M.P.E.P. § 1205.2:

I. REAL PARTY IN INTEREST

The real party in interest for this appeal is C. R. Bard, Inc., the assignee of record.

II. RELATED APPEALS AND INTERFERENCES

There are no other appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in this appeal.

III. STATUS OF CLAIMS

A. Total Number of Claims in Application

There are 18 claims pending in application.

B. Current Status of Claims

1. Claims canceled: 1-29
2. Claims withdrawn from consideration but not canceled: 34-39
3. Claims pending: 30-47
4. Claims allowed: none
5. Claims rejected: 30-33 and 40-47

C. Claims On Appeal

The claims on appeal are claims 30-33 and 40-47.

IV. STATUS OF AMENDMENTS

Appellant did not file an Amendment After Final Rejection. Accordingly, all amendments submitted to date have been entered and considered.

V. SUMMARY OF CLAIMED SUBJECT MATTER

The current application was restricted during prosecution to FIGS. 7A-7D, as amended. Accordingly, the present description is restricted to the elected embodiment. However, the scope of the present claims are determined by the recited limitations and not a reliance on the restricted subject matter used during prosecution. Accordingly, Appellant does not intend to restrict or limit the claimed subject matter or the corresponding scope based on the described embodiment.

This invention relates in one aspect to a catheter assembly (p. 3, ¶ [0014], l. 1), including a catheter with at least one lumen (p. 3, ¶ [0014], l. 2), and a connector including a distal end attached to a proximal end of the catheter and a passageway in fluid communication with the at least one lumen (p. 3, ¶ [0014], l. 2), a proximal portion of the passageway including an engagement feature configured to connect an end of an instrument to the connector (p. 9, ¶ [0047], ll. 11-13), a distal portion of the passageway including a built-in valve longitudinally fixed with respect to the connector having a closed proximal end with a slit and an open distal end (FIGS. 7A-7D; p. 7, ¶ [0041], ll. 2-5), the valve proximal end distal of the engagement feature (FIG. 7D).

The catheter assembly, as claimed in dependent claim 32, may further comprise materials selected such that the connector comprises a material having a hardness in the range of about 90 Shore A to about 90 Shore D, and the valve comprises a material having a hardness in the range of about 40 Shore A to about 60 Shore A (p. 7, ¶ [0041], ll. 11-13).

The catheter assembly, as claimed in dependent claims 33, 40 and 41, may include additional features. For example, the engagement feature of the catheter assembly may be an O-ring, and a wall defining the proximal portion of the passageway proximal of the O-ring may be tapered (p. 9, ¶ [0047], ll. 11-13, FIG. 7D). The connector outer surface at a proximal end may also be tapered (p. 9, ¶ [0147], ll. 13-15). The catheter assembly may also comprise a syringe adaptor including a distal end configured to slide over the tapered proximal end of the connector housing and a proximal opening to receive a male luer (p. 47, ¶ [0047], ll. 5-9; FIGS. 7A-7B).

VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

A. Whether claim 30 is indefinite under 35 U.S.C. § 112, second paragraph?

B. Whether claims 30, 40, 42-47 are unpatentable under 35 U.S.C. § 103 over Wilson in view of Krug?

C. Whether claims 30, 40, 42-47 are unpatentable under 35 U.S.C. § 103 over Wilson in view of Duncan?

D. Whether claims 30-33, 40-41, 43-46 are unpatentable under 35 U.S.C. § 103 over Canaud?

VII. ARGUMENT

A. Claim 30 rejected as indefinite under 35 U.S.C. § 112, second paragraph

The Examiner has rejected claim 30 based on the recitation of "an engagement feature," asserting that it is unclear which element is considered. (Office Action, p. 3.) However, the Examiner then interprets the "engagement feature" as something to hold/connect with an instrument. (Office Action, p. 3.)

"The examiner's focus during examination of claims for compliance with the requirement for definiteness of 35 U.S.C. 112, second paragraph, is whether the claim meets the threshold requirements of clarity and precision, not whether more suitable language or modes of expression are available. … Some latitude in the manner of expression and the aptness of terms should be permitted even though the claim language is not as precise as the examiner might desire." (MPEP § 2173.02.) "In reviewing a claim for compliance with 35 U.S.C. 112, second paragraph, the examiner must consider the claim as a whole to determine whether the claim apprises one of ordinary skill in the art of its scope and, therefore, serves the notice function required by 35 U.S.C. 112, second paragraph, by providing clear warning to others as to what constitutes infringement of the patent." (Id. citing *Solomon v. Kimberly-Clark Corp.*, 216 F.3d 1372, 1379 (Fed. Cir. 2000).)

Claim 30 recites "an engagement feature configured to connect an end of an instrument to the connector." Appellant respectfully submits that a feature defined to connect an end of an

instrument to the claimed connector is clear and precise. As illustrated by the Examiner, this feature may be something to hold/connect with an instrument. Further specifics of this feature are described in the dependent claims, such as, for example, claim 33 reciting an O-ring. Further restriction to the engagement feature is unnecessary for the understanding of the independent claim.

B. Claims 30, 40, 42-47 rejected under 35 U.S.C. § 103 over Wilson in view of Krug

The Examiner has rejected claims 30, 40, and 42-47 under 35 U.S.C. § 103(a) as obvious over US 6,921,396 to Wilson et al. ("Wilson") in view of US 4,502,502 to Krug ("Krug"). Wilson admittedly fails to disclose the built-in valve recited by claim 30. (Office Action, p. 7.) However, Krug does not provide the built-in valve in the configuration as claimed. Specifically, to permit fluid flow as required by Wilson, the Krug valve provides the exact opposite configuration in which the distal end is closed and the proximal end is open. If the valve orientation is as claimed, the Wilson device becomes inoperable for its intended purpose. As such, the cited references of Wilson in view of Krug do not support a *prima facie* case of obviousness.

Wilson shows and describes a multi-lumen catheter 10 including a catheter tube 16, a flush tube portion 14, and a connector 12. (Wilson, col. 7:29-31.) "The connector 12 and the flush tube portion 14 permit the simultaneous flushing of the multiple lumens 30 of the catheter tube 116 with a flushing liquid 62." (Wilson, col. 8:61-63.) FIG. 8, used in the rejection of the present claims, is annotated below with the fluid flow required by the flushing fluid injected into the catheter as described by Wilson, above.

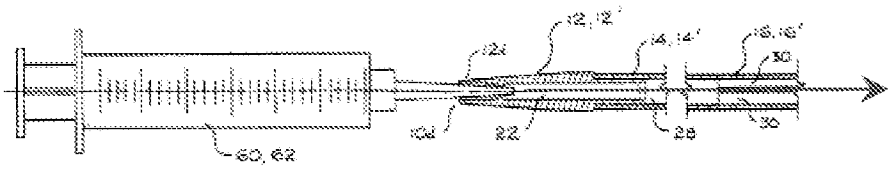
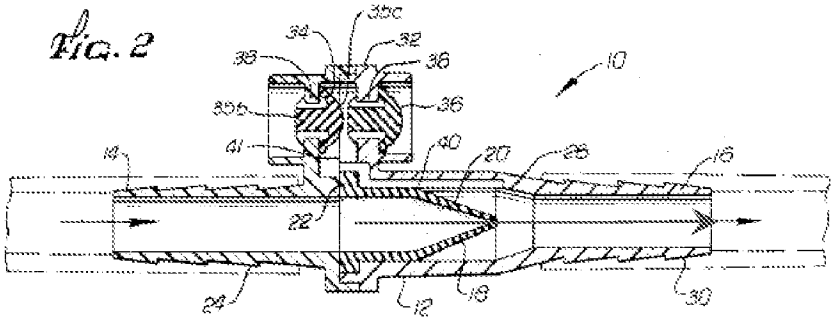


FIG. 8

Krug shows and describes an overpressure safety valve assembly for use during heart surgery. (Krug, Abstract.) The "overpressure safety valve assembly 10 ... is comprised of an elongated tubular body portion 12 having an inlet end 14 and an outlet end 16. A unidirectional

flow regulator or valve 18 is axially disposed in the body 12 along the length thereof. Such unidirectional valve 18 is well known and recognized in the art sometimes being referred to as a 'duckbill' valve." (Krug, col. 2:31-35.) As seen in Krug FIG. 2, the fluid flow path through the valve is identified by arrows.



In order to permit the fluid flow to flush the catheter as described by Wilson, the Krug valve would have to be inserted such that the closed end of the valve is downstream. This results in essentially FIG. 2 of Krug overlaid on FIG. 8 of Wilson. However, as claimed, the connector distal end is attached to the catheter while the passageway proximal portion includes the engagement feature. As such, Wilson FIG. 8 illustrates the proximal end to the left of the figure and the distal end to the right toward flushing tube 14. If the Krug valve is overlaid onto FIG. 8, the right end of the valve, i.e. the distal end, is closed, while the left end, i.e. the proximal end, is open. This configuration is in direct contradiction to the claimed configuration. Accordingly, the cited references do not show or describe the claimed configuration.

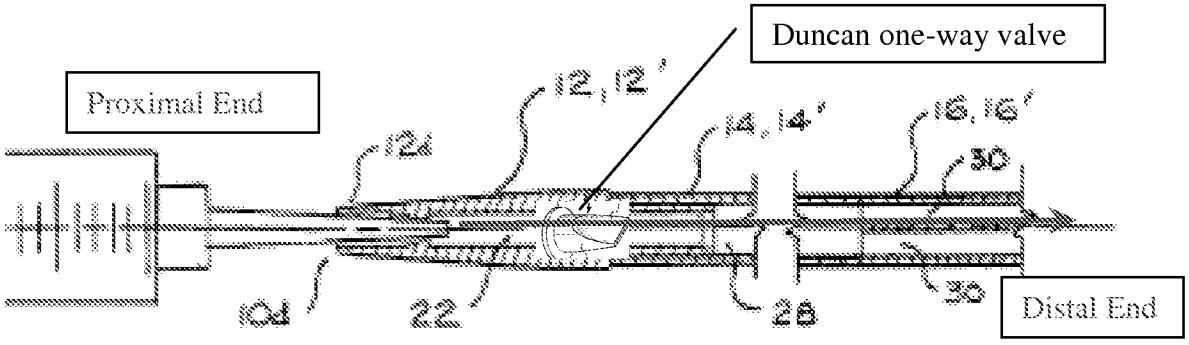
If the Krug valve were inserted into the Wilson device to meet the claimed limitation, the connector would prevent fluid flow in direct contradiction to the purpose of the Wilson connector (i.e. to permit flushing of the catheter lumens). Such a configuration would render the Wilson connector unsatisfactory for its intended purpose. Accordingly, such a modification is prohibited pursuant to MPEP § 2143.01, i.e., "[i]f the proposed modification or combination of prior art would change the principle of operation of the prior art invention being modified, then the teachings of the references are not sufficient to render the claims *prima facie* obvious." (MPEP § 2143.01.)

In view of the above, the combination of Wilson in view of Krug is insufficient to support of *prima facie* case of obviousness at least because the claimed configuration is not suggested by the references. As such, claim 30 and claims 40, and 42-47, depending therefrom, are believed patentable over the combination of Wilson in view of Krug.

C. Claims 30, 40, 42-47 rejected under 35 U.S.C. § 103 over Wilson in view of Duncan

The Examiner alternatively rejected claims 30, 40, and 42-47 under 35 U.S.C. 103(a) as obvious over Wilson in view of USPN 4,535,818 to Duncan et al. (hereinafter, "Duncan"). However, Duncan discloses the same duckbill valve, and thus suffers from the same deficiencies as Krug. Specifically, if the Duncan valve is combined with Wilson to permit the proper fluid flow to flush the catheter as required by Wilson, the valve is in the direct opposite configuration than claimed. If the Duncan valve is inserted into the Wilson device oriented as claimed, then the fluid flow path is restricted, thus rendering the Wilson device inoperable for its intended flushing purpose.

Duncan shows and describes a "valve assembly for use within a flow path for permitting relatively free flow in the flow path in a first direction and for preventing flow in the path in a second, opposite direction." (Duncan, col. 2:51-54.) The housing interior is also provided so that "flow in the first direction is from the first port, through the open end, through the normally closed end, and to the second port." (Duncan, col. 3:1-4.) As such, the Duncan valve has an open end upstream of the fluid flow and a closed end downstream.



As shown above by the annotated Wilson FIG. 8 overlaid with Duncan FIG. 4A, the asserted combination results in a connector having a valve with a closed distal end and open proximal end, in direct contradiction to the claimed configuration. Otherwise, the Duncan valve prevents fluid flow through the connector and the desired flushing of the connected catheter, in direct contradiction to the teach of Wilson. Accordingly, the references do not support a *prima facie* case of obviousness with respect to independent claim 30. As such, claim 30 and claims 40, and 42-47, depending therefrom, are believed patentable over the combination of Wilson in view of Duncan.

D. Claims 30-33, 40-41, 43-46 rejected under 35 U.S.C. § 103 over Canaud

The Examiner has rejected claims 30-33, 40-41, and 44-46 under 35 U.S.C. § 103(a) as obvious over US Pub. No. 2004/0193119 to Canaud et al. (hereinafter, "Canaud"). Appellant does not appeal the rejections with respect to claims 30-31, and 43-46. However, the features of dependent claims 32-33, and 40-41 are not suggested by Canaud, such that review of these rejections is respectfully requested. Claim 47 is also rejected under 35 U.S.C. § 103(a) as obvious over Canaud in view of Wilson. Appellant does not appeal the rejection of this claim.

1. Claim 32

The cited combination admittedly fails to show or describe the features of dependent claim 32, including "the connector compris[ing] a material having hardness in the range of about 90 Shore A to about 90 Shore D, and … the valve compris[ing] a material having a hardness in the range of about 40 Shore A to about 60 Shore A." To overcome this deficiency, the Examiner relies on the precedent of *In re Leshin*, holding that it is within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. (Office Action, pp. 4-5.) However, the facts between the precedent and the present application are sufficiently different that the legal conclusion is not rationally supported.

The reliance on legal precedent, *In re Leshin*, is misplaced, as that case discusses the suitability of a known material, and not the variations of material properties as the Examiner is attempting to interchange. In order to rely on legal precedent, the facts in a prior legal decision

must be sufficiently similar to those in an application to use the rationale of the court. (MPEP 2144.04.) The court of *In re Leshin*, 227 F.2d 197, 125 USPQ 416 (CCPA 1960), held that a selection of a known plastic to make a container of a type made of plastics was obvious. (MPEP 2144.07.) Here, the Examiner has manufactured a material property, i.e. hardness, within the claimed range without any hint of a desired material or the desirability of the associated material property. Therefore the facts of the precedent is sufficiently different (i.e. manufacturing a material property from nothing) to use the rationale of the court (obviousness of utilizing a specific material from the identified general material).

Alternatively, an obviousness determination based on a known material on the basis of its suitability for an intended use requires a recognition within the art of a known material and the desired properties consistent with the claimed material. (*See*, MPEP 2144.07, "Art Recognized Suitability for an Intended Purpose.") Again, the Examiner is not attempting to interchange materials, but material properties, without identifying the art recognized desired property. Accordingly, the conclusory assertion that the claimed subject matter is obvious is *prima facie* unsupported.

2. Claim 33

Dependent claim 33 recites "a wall defining the proximal portion of the passageway proximal of the O-ring is tapered." As recited by independent claim 30, the distal end of the connector is attached to the catheter, and thus corresponds to the right end of the Canaud FIG. 3, below. However, as seen in the annotated Canaud FIG. 3 provided by the Office, reproduced below, the indicated tapered portion is distal to the asserted O-ring position, in contradiction to the present claims. Accordingly, the claimed configuration is not shown or suggested by the cited references.

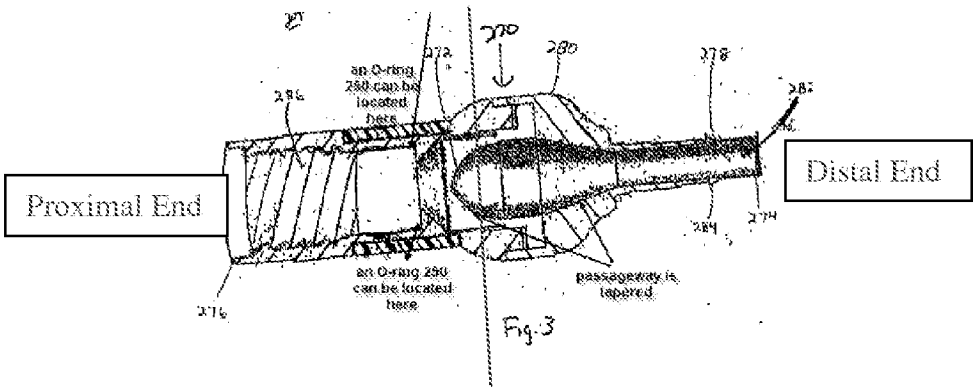


Fig. 3

3. Claim 40

With respect to dependent claim 40, the Office states that "Canaud also discloses [that] the connector 270 includes a tapered outer surface (at portion of element 280 in Fig. 3) at a proximal end thereof." (Office Action, p. 6.) However, as seen from the annotated Figure, reproduced above, section VII.D.2, the tapered surface is past the middle section of the device (middle annotated by a red vertical line), toward the distal end. Accordingly, even assuming *arguendo* that a middle section of the device may be considered the proximal end, a middle section not even past center toward the proximal side is not a tapered outer surface as claimed.

4. Claim 41

With respect to dependent claim 41, Canaud fails to suggest the claimed "syringe adaptor including a distal end configured to slide over the tapered proximal end of the connector housing." The Examiner presents the following line of reasoning to support a *prima facie* case of obviousness with respect to the adaptor connection to the connector housing: (1) the recitation of "configured to/adapted to/capable of" performing a function does not constitute a limitation in any patentable sense; (2) other ways in the art are used to engage two elements instead of a the disclosed threaded connection, i.e. such as by friction fit; (3) a distal end of the syringe adaptor either sliding over or into the proximal end of the connector is considered a rearrangement of parts or constructing a structure in various elements, which involves only routine skill in the art. Appellant respectfully disagrees, and submits such conclusory statements without verification cannot support a *prima facie* case of obviousness.

The Office fails to show the claimed configuration of a syringe adaptor including a distal end configured to slide over the tapered proximal end of the connector housing. Therefore, such a modification to the Canaud port is not merely a rearrangement of parts or structuring into multiple elements, as asserted by the Office to support a *prima facie* case of obviousness, but instead is a feature not shown or described by the cited combination of references.

E. Conclusion

Appellant respectfully submits that the Office has not established a *prima facie* case of anticipation/obviousness with respect to claims 30, 40, and 42-47 over Wilson in view of either Krug or Duncan or claims 32-33, and 40-41 over Canaud for at least the reasons set forth herein. Accordingly, these claims are patentable over the respective cited art. Favorable action is solicited and a withdrawal of the rejections to these claims is respectfully requested.

VIII. CLAIMS

A copy of the claims involved in the present appeal is attached hereto as Appendix A. As indicated above, the claims in Appendix A include the amendments filed by Applicant on March 22, 2010; April 27, 2009; September 29, 2008; and October 25, 2007.

Dated: May 31, 2011

Respectfully submitted,

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APPENDIX A

Claims Involved in the Appeal of Application Serial No. 10/803,512

Listing of Claims:

1-29. (Canceled).

30. (Previously presented) A catheter assembly, comprising:

a catheter including at least one lumen; and

a connector including a distal end attached to a proximal end of the catheter and a passageway in fluid communication with the at least one lumen, a proximal portion of the passageway including an engagement feature configured to connect an end of an instrument to the connector, a distal portion of the passageway including a built-in valve longitudinally fixed with respect to the connector having a closed proximal end with a slit and an open distal end, the valve proximal end distal of the engagement feature.

31. (Previously presented) The catheter assembly according to claim 30, wherein the valve includes a wall defining a lumen from the proximal end to the distal end, the wall configured to guide a proximal end of a guidewire from the valve distal end through the slit in the valve proximal end.

32. (Previously presented) The catheter assembly according to claim 30, wherein the connector comprises a material having a hardness in the range of about 90 Shore A to about 90 Shore D, and wherein the valve comprises a material having a hardness in the range of about 40 Shore A to about 60 Shore A.

33. (Previously presented) The catheter assembly according to claim 30, wherein the engagement feature comprises an O-ring, and wherein a wall defining the proximal portion of the passageway proximal of the O-ring is tapered.

34. (Withdrawn) A catheter assembly, comprising:

a catheter including a first lumen and a second lumen; and

a connector including a distal end attached to a proximal end of the catheter, a distal portion of the connector including a collapsed portion biasing a lumen of the connector in a closed configuration.

35. (Withdrawn) The catheter assembly according to claim 34, wherein a proximal portion of the connector lumen includes an engagement feature configured to connect an end of an instrument to the connector.

36. (Withdrawn) The catheter assembly according to claim 34, wherein the connector comprises a material having a hardness in the range of about 60 Shore A to about 90 Shore A.

37. (Withdrawn) An adaptor assembly, comprising:

a connector housing including a tapered proximal end and a distal end having an opening configured to receive a proximal end of a catheter, a distal portion of a connector housing lumen including a valve having a closed proximal end with a slit and an open distal end; and

a syringe adaptor including a distal end configured to slide over the tapered proximal end of the connector housing and a proximal opening configured to receive a male luer portion of the syringe.

38. (Withdrawn) The adaptor assembly according to claim 37, wherein a proximal portion of the connector housing lumen includes an engagement feature configured to connect an end of a tunneler to the connector housing, the valve proximal end distal of the engagement feature.

39 (Withdrawn) The adaptor assembly according to claim 37 in combination with a tunneler, wherein the engagement feature comprises a compression ring configured to grip a tip of the tunneler.

40. (Previously presented) The catheter assembly according to claim 30, wherein the connector includes an tapered outer surface at a proximal end thereof.

41. (Previously presented) The catheter assembly according to claim 40, further comprising a syringe adaptor including a distal end configured to slide over the tapered proximal end of the connector housing and a proximal opening to receive a male luer.

42. (Previously presented) The catheter assembly according to claim 30, further comprising a tunneler, wherein the engagement feature engages a tip of the tunneler upon insertion of the tunneler tip into the proximal portion of the passageway.

43. (Previously presented) The catheter assembly according to claim 30, wherein the valve opens by insertion of a medical device through the valve.

44. (Previously presented) The catheter assembly according to claim 30, wherein the valve proximal end is longitudinally fixed with respect to the connector.

45. (Previously presented) The catheter assembly according to claim 30, wherein the valve proximal end is fixed relative to the engagement feature.

46. (Previously presented) The catheter assembly according to claim 30, wherein the engagement feature includes a projection into the passageway.

47. (Previously presented) The catheter assembly according to claim 46, wherein the projection has a reduced diameter relative to an inside diameter of the passageway on a proximal side and a distal side of the projection.

APPENDIX B

No evidence pursuant to §§ 1.130, 1.131, or 1.132 or entered by or relied upon by the examiner is being submitted.

APPENDIX C

No related proceedings are referenced in II. above, hence copies of decisions in related proceedings are not provided.